

REMARKS

This Amendment Under 37 C.F.R. §1.115 is respectfully submitted in response to the Office Action dated January 29, 2003. It is timely submitted in view of the Petition for Extension of Time submitted concurrently herewith.

The claims have been amended in order to cancel the non-elected claims without prejudice and for reasons unrelated to patentability. Applicants respectfully reserve the right to file such claims in divisional applications in the future. The claims have also been amended in order to remove reference to "soybean milk", which subject matter is being prosecuted in co-pending patent application Serial No. 09/206,249. Claim 24 has been amended to add the phrase "in need thereof" to indicate that the cells to which the claim refers are in need of the therapeutically phagocytosis- or ICAM-1 decreasing effective amount of the claimed composition. Basis for this amendment may be found in the Specification at pages 9, l. 22 - page 10, l. 20. Claims 24, 29, 30, 38, 40, 45 and 46 have been amended to add the phrase "containing STI" to the term "soybean paste" in order to clarify the meaning of the claim. Basis for this amendment may be found in the Specification at page 17, l. 19-27.

The Office Action of January 29, 2003 provisionally rejected claims 24, 28-30, 38, 40 and 44-46 under 35 U.S.C. 102(e) as being anticipated by copending Application Serial No. 09/110,409 on the ground that it "discloses the composition of STI (soy trypsin inhibitor) and a cosmetically acceptable carrier/vehicle and discloses a method of using the composition which inherently will decrease phagocytosis or ICAM-1 expression in a mammalian cell as in the instant application." [Office Action of 1/29/2003, p. 3]. Applicants respectfully request reconsideration of this rejection in light of the ensuing remarks.

Applicants respectfully submit that although U.S. Application Serial No. 09/110,409 describes a composition containing STI, nowhere therein is there a description or suggestion that such compositions may be useful for decreasing phagocytosis or ICAM-1 expression in a mammalian cell **in need thereof**, i.e., for preventing or treating a mammal afflicted or which might be afflicted with a disorder ameliorated by a decrease in phagocytosis, **in an amount effective to decrease phagocytosis or ICAM-1 expression** [Specification, p. 10, l. 1-6]. Thus, applicants respectfully

submit that Serial No. 09/110,409 does not anticipate the subject matter of the claims herein.

Furthermore, Miri Seiberg and Stanley Shapiro were inventors of the cited patent application Serial No. 09/110,409. Upon issuance of a patent based upon Serial No. 09/110,409, applicants respectfully offer to submit a showing if deemed necessary. Applicants respectfully request reconsideration of the rejection under 35 U.S.C. §102(e) in light of the foregoing discussion.

The Office Action of January 29, 2003 rejected claims 24, 28-30, 38, 40, and 44-46 under 35 U.S.C. §102(b) as being anticipated by Holmgren et al. (col. 17), Hammonds, Jr. et al. (col. 36) and Hammonds, Jr. et al. (col. 37) on the ground that each teaches "administering STI to a patient" [Office Action, 1/29/2003, p. 4]. Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Holmgren describes an "immunological tolerance-inducing agent comprising a mucosa-binding molecule linked to a specific tolerogen..." [Holmgren, Abstract, l. 1-3]. The only mention of STI in Holmgren is in connection with an example purportedly demonstrating "suppression of experimental autoimmune encephalitis (EAE) by oral administration of myelin basic protein conjugated to CTB" [Holmgren, col. 15, l. 55-57]. STI was administered to a control group of animals in the study as follows:

In control animals previously fed with soybean trypsin inhibitor (STI) (group 4), given 11, 9, 7, 5 and 3 days before footpad injection with MBP+FCA, neurological symptoms developed being maximal 12 to 14 days after the injection and all animals developed severe paralysis...[Holmgren, col. 17, l. 1-5]

Although Holmgren states that STI is fed to rats, it was given to a control group to compare the rats' reaction to certain proteins. The rats ultimately developed severe paralysis: their condition did not improve. Nowhere does Holmgren suggest or describe a method of preventing or treating a mammal afflicted or which might be afflicted with a disorder ameliorated by a decrease in phagocytosis, in an amount effective to decrease phagocytosis or ICAM-1 expression. Applicants therefore respectfully request reconsideration of this rejection.

Nor do the Hammonds, Jr. et al. patents describe or suggest the methods of applicants' invention. The Hammonds, Jr. et al. patents relate to the purification of growth hormone receptor and growth hormone

binding protein [Abstract, l. 1-2]. Nowhere does either Hammonds, Jr. et al. patent suggest or describe a method of preventing or treating a mammal afflicted or which might be afflicted with a disorder ameliorated by a decrease in phagocytosis, in an amount effective to decrease phagocytosis or ICAM-1 expression. Rather, the Hammonds, Jr. et al. patents merely indicate the use of STI and/or other proteins in **conjugate forms** with the serum binding protein for the purpose of immunization as the protein, as follows:

Therefore, a multi-step screening process would be used. Antibodies to the binding protein would be obtained. Animals are **immunized against the binding protein or to selected fragments thereof in conjugate form with such proteins as keyhole limpet hemogalin (KLH), bovine serum albumin (BSA), soybean trypsin inhibitor (STI) or bovine thyroglobulin (BT)**...[Hammonds, Jr., et al., U.S. Patent No. 5,057,417, col. 37, l. 36-43] (emphasis added)

Hammonds, Jr., et al. U.S. Patent No. 5,688,763 at col. 36, l. 20-26 has the identical statement. Thus, the Hammonds, Jr. et al. patents not only do not suggest or describe a method of preventing or treating a mammal afflicted or which might be afflicted with a disorder ameliorated by a decrease in phagocytosis, in an amount effective to decrease phagocytosis or ICAM-1 expression, they only state that a conjugate of STI and serum binding protein was administered. Applicants therefore respectfully request reconsideration of this rejection.

The Office Action of January 29, 2003 further rejected claims 24, 28-30, 38, 40, and 44-46 under 35 U.S.C. §102(e) as being anticipated by Costanzo. Applicants respectfully request reconsideration of this rejection in light of the ensuing discussion.

Applicants respectfully submit that the parent application of this application is a nonprovisional application based upon provisional application Serial No. 60/069,797, filed December 16, 1997, several months before the application on which Costanzo issued was filed. In fact, the Costanzo patent application was based in part upon that provisional application. Applicants respectfully submit that, as the Costanzo application was filed after the original provisional application on which the subject application was based, Costanzo cannot serve as a reference under 35 U.S.C. §102(e). Applicants therefore respectfully request reconsideration of this rejection.

The Office Action of January 29, 2003 further rejected claims 24, 28-30, 38, 40, 44-46 provisionally under 35 U.S.C. §101 as claiming the

same invention as that of claims 1-25 and 56-59 of copending Application No. 09/110,409. Applicants respectfully request reconsideration of this provisional rejection.

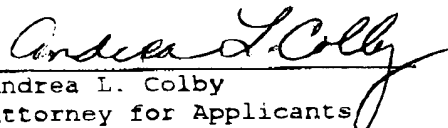
Applicants respectfully submit that, as stated above, the 09/110,409 application neither suggests nor describes a method of preventing or treating a mammal afflicted or which might be afflicted with a disorder ameliorated by a decrease in phagocytosis, in an amount effective to decrease phagocytosis or ICAM-1 expression. Applicants further respectfully suggest that such a rejection under 35 U.S.C. §101 is premature and should be withheld until the claims of 09/110,409 are issued in a patent.

The Office Action of January 29, 2003 also provisionally rejected claims 24, 28-30, 38, 40, 44-46 under the judicially created doctrine of obviousness-type double patenting over claims 1-25, 56-59 of copending Application Serial No. 09/110,409. Applicants respectfully request reconsideration of this rejection.

Applicants respectfully submit that Serial No. 09/110,409 neither suggests nor describes the methods of applicants' invention. Nowhere therein is there a suggestion that STI or other members of the delineated Markush group of the claims would be useful in treating or preventing disorders ameliorated by decreasing phagocytosis or ICAM-1 expression. Applicants respectfully submit that, again, this rejection is premature and should be held in abeyance until claims of 09/110,409 are issued in a patent. Applicants respectfully submit that they could not present claims corresponding to those of the instant application in the other copending application in light of the fact that the claims of the instant application would require basis in the Specification for treating or preventing disorders ameliorated by decreasing phagocytosis or ICAM-1 expression. Applicants respectfully request reconsideration of the rejections under 35 U.S.C. §101 and the judicially created doctrine of obviousness-type double patenting in view of the foregoing discussion.

In view of the foregoing discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of January 29, 2003. An early allowance is earnestly solicited.

Respectfully submitted,

  
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